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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,979	02/12/2001	Parula Mehta	98,375-C	1569
20306 7590 05/03/2007 MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP 300 S. WACKER DRIVE 32ND FLOOR CHICAGO, IL 60606			EXAMINER LUCAS, ZACHARIAH	
			ART UNIT 1648	PAPER NUMBER
			MAIL DATE 05/03/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/701,979

Applicant(s)

MEHTA ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 4-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, and 4-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Claims 1, 2, and 4-13 are pending and under consideration.
2. This action is in response to the remand from the Board of Appeals mailed on January 31, 2007. In view of the remand, the finality of the action mailed on July 27, 2004 is withdrawn.

In view of the Restatement of the rejection of record, this action is made Non-Final.

#### *Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **(Prior Rejection- Restated and Maintained)** Claims 1, 2, and 4-13 were rejected in the prior action under 35 U.S.C. 103(a) as being unpatentable over McCormick in view of McManus and Stokes. In view of the Applicant's arguments, and for the reasons indicated in the Remand from the Board of Patent Appeals on January 31, 2007, the rejection is restated as a rejection of the claims over McCormick (U.S. Patent 3,431,886) in view of Copeland (U.S. Patent 5,650,327), and in view of McManus et al. (Staining Methods, Histologic and Histochemical, Paul B. Hoeber, Inc., New York, 1960), Stokes et al. (U.S. 5,318,795), and Woods and Ellis (Laboratory Histopathology: A Complete Reference, "Haematoxylin and Counterstains", Churchill Livingstone, 1994). The claims read on automated methods of staining biological

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materials on a slide comprising providing a first and second unstable solution, and providing a slide with a biological material to be stained, and sequentially applying the first and second solutions to the material such that an unstable solution is formed in contact with the material.

As was previously indicated McCormick teaches an automated method for the staining of biological materials on a slide comprising the provision of a plurality of staining solutions, a slide having a biological specimen thereupon, and an automated stain delivery system, and the sequential application of the different solutions to the specimen. See column 1 lines 36-45, and column 2 lines 6-40. However, the reference does not teach the sequential application to the specimen of a plurality of stable solutions, which solutions when mixed create an unstable staining solution.

McManus provides teachings relating to standard staining solutions in the art. See e.g., pages 134, 138, 149, 228, and 240. Further, the reference teaches the mixing of these stains just prior to use from stable stock reagents, and indicates that the stains are unstable over time. Pages 134 (step 2), 135 (step 4), 138 (step 2), 240 (description paragraph for Verhoeff's Elastic Tissue Stain), and 368 (step 5). Thus, the mixing of stable reagents to achieve an unstable staining solution was known in the art. Further, it was also known in the art to mix such reagents immediately prior to use. However, although this reference demonstrates that the use of unstable stains formed by mixing stable reagents was known, the reference does not teach the use of such stains in an automated method.

The rejection was remanded to the Examiner for further clarification as to why it would have been obvious to those of ordinary skill in the art to mix stable components directly on a sample to form an unstable histochemical staining solution. As was previously indicated by the

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Examiner, each of the Copeland and Stokes references describe methods for the automated staining of biological specimens on slides, and teach the automated mixing of multiple reagents directly on the slide.

In addition to these teachings of record, pages 5.2-8 of Woods and Ellis teaches that separated reagents for some dyes (e.g., iron haematoxylin) are shelf stable, and that iron haematoxylin stain solutions are unstable. Moreover, the reference teaches the sequential addition of the different reagents to a sample (i.e. mixing of the stable reagents directly on the slide to result in an unstable dye). Page 5.2-9. Thus, this reference demonstrates that it was known in the art to mix stable reagents to form an unstable dye on the sample to be stained. The teachings of this reference, in addition to those of the Copeland and Stokes references as previously described, indicate that it would have been obvious to those of ordinary skill in the art to sequentially apply multiple stable reagents to sample on a slide so as to result in the making of an unstable dye, which will in turn stain the indicated sample. Thus, contrary to the Applicant's assertions, the art indicates that multiple stable reagents may be applied to a sample to form a dye on the sample.

It would therefore have been obvious to those of ordinary skill in the art to use the automated methods of McCormick, Copeland, and Stokes for the sequential addition of multiple reagents to a sample so as to result in an unstable dye. Those in the art would have been motivated to make such a combination based on the teachings of McManus indicating that those in art knew to make such unstable dyes as close to the time of actual use as possible, and the teachings of each of Copeland, Stokes, and Woods and Ellis teaching that the sequential application of reagents, including stable reagents, to a slide containing a sample so as to form an

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unstable dye which would stain the target sample. For these reasons, and for the reasons of record, the Applicant's assertion that the rejection is based on the use of improper hindsight is not found persuasive.

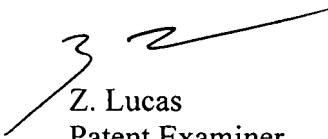
The rejection as restated is therefore maintained.

***Conclusion***


5. No claims are allowed.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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